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Hazard Evaluation Division
Standard Evaluation Procedure
Non-Target Plants
Terrestrial Field Testing - Tier 3

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The Standard Evaluation Procedure for Non-Target Plants: Terrestrial Field Testing - Tier 3, a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Standard Evaluation Procedure (SEP), prescribes the evaluation criteria and procedures to assess this pesticide phytotoxicity study that the US Environmental Protection Agency recommends to support the registration of manufacturing-use and formulated end-use products. This SEP, in conjunction with the Pesticide Assessment Guidelines, Subdivision J, is designed to aid data reviewers in their evaluation of terrestrial field testing studies submitted by registrants. A summary of the rule-making phytotoxicity test requirements can be found in 40 CFRPart 158. The study results contained in the evaluation procedure together with environmental fate and efficacy data are used to assess the potential hazard of pesticides to terrestrial and aquatic non-target plants.

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

NON-TARGET PLANTS:

TERRESTRIAL FIELD TESTING - TIER 3

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NON-TARGET PLANTS: TERRESTRIAL FIELD TESTING - TIER 3

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid Ecological Effects Branch (EEB) data reviewers in their evaluations of Tier 3 terrestrial field testing plant studies submitted by registrants in the assessment of pesticide effects on non-target plants.

B. Background Information

Terrestrial field testing (Tier 3) studies are designed to provide phytotoxicity data on a pesticide. These phytotoxicity data are needed to evaluate the level of pesticide exposure to non-target terrestrial plants and to assess the impact of pesticides on endangered and threatened plants as noted under the Endangered Species Act. Where a phytotoxic effect is noted in one or more plants, additional terrestrial field testing studies may be required. These data are required by 40 CFR § 158.150 to support the registration of any pesticide intended for outdoor use under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

Pesticides with outdoor use patterns that do not readily release the pesticide to the environment do not have to be evaluated using this phytotoxicity test. These use patterns include tree injection, subsurface soil applications, recapture systems, wick applications, and swimming pool uses. If any of these use patterns do readily expose non-target plants to the pesticide, as through vapors, the pesticide phytotoxicity potential may need to be evaluated.

C. Objective of the Terrestrial Field Testing Tier 3 Test

The objective of the Tier 3 terrestrial field testing study is to determine if a pesticide exerts a detrimental effect to plants during critical stages in their development. The test is performed on species from a cross-section of the non-target terrestrial plant population. This is a multiple dose test designed to evaluate the phytotoxic effects of the pesticide over a wide range of anticipated pesticide quantities as may be found in the environment.

II. INFORMATION TO BE SUPPLIED

The registrant's report on terrestrial field testing studies should include all information necessary to provide: 1) a complete and accurate description of the laboratory/greenhouse treatments and procedures, 2) sampling data and phytotoxicity rating, 3) data on storage of the plant material until analysis, if so performed, 4) any chemical analysis of the plant material as to chemical content, if so performed, 5) reporting of the data, rating system and

statistical analysis, and 6) quality control measures/precautions taken to ensure the fidelity of the operations.

A guideline of specific information that should be included in the registrant's report of terrestrial field testing studies is provided in Appendix 1 of this document. The lists of requested information and reviewer aids are derived from the Pesticide Assessment Guidelines, Subdivision J: Hazard Evaluation of Non-Target Plants, which is complemented by this Standard Evaluation Procedure.

III. DATA INTERPRETATION

The acceptability of the study results will depend upon whether the test requirements/standards are followed. If a deviation is made, a determination must be made as to whether the deviation has changed the quality of the results in such a manner that the results cannot be extrapolated to the natural environment. There should be little or no deviation from the liberalized standards prescribed in this study.

The results of the phytotoxicity test of the chemical with respect to the quantity applied to the foliage are important. The concentration of the chemical in the carrier is important in that stronger concentrations than normally used can lead to burning and necrosis. Subtoxic concentrations, on the other hand, may also cause unwanted rapid growth.

Plants can recover from certain types of injury that will have little or no effect on the esthetic or economic value of the plant(s) tested or to which an evaluation is made. Therefore, it is important that a minimum of two weeks of observations be made after application of the pesticide; three to four weeks are preferable.

A decision point to perform additional Tier 3 terrestrial tests is a 25% detrimental effect, i.e., a 25% change in plant growth or injury as compared to untreated controls. This level is considered to be that point at which the plants will not recover to their full esthetic value, economic value or reproductive potential as in the case of the maintenance of the endangered or threatened species.

IV. THE DATA EVALUATION PROCESS

Upon careful examination of the information/data supplied by the registrant in his submission to the Agency, the reviewer shall evaluate the data as follows.

A. Identify Data Gaps

Using Appendix 1 of this document as a guide, the reviewer should look for data gaps - omissions in the information supplied

by the registrant in his report. These should be duly noted in the reviewer's report, and a judgment made as to which are considered significant enough to adversely affect the review process. Those so identified should be communicated back to the registrant by the Product Manager for corrective action.

B. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness, i.e., the intended use pattern, and adequacy of the data/information that has been supplied. Appendix 1 of this document is a useful guide to the various parameters that need to be considered. Appendix 2 provides specific questions that should be answered by the reviewer during the study evaluation process. Statistical treatments of the data should be independently verified and the quality control precautions noted.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available. (See also the recommended references in Subdivision J - Hazard Evaluation: Non-Target Plants.) A listing of additional source materials is located in the References section of this document.

In addition to the data gaps noted above, any perceived deficiencies in the data/information supplied should also be identified. A statement as to these deficiencies should be made in the reviewer's report and corrective action to resolve them should be provided. This information can be relayed to the registrant by the Product Manager for appropriate action.

C. Report Preparation

The Agency reviewer prepares a standard review report following the standard format for preparation of scientific reviews as provided in Appendix 3 of this document. All important information provided by the registrant including the methodology and results should be summarized in order that future evaluations can be made. The results may be expressed in the form of tables where specific values are related. Figures (graphs) may be provided but are not to be the sole source of the values needed for future evaluations.

D. Conclude if the Requested Action is Supportable

Lastly, the reviewer considers the results of the terrestrial field testing studies and makes a judgment as to whether they support the requested registration action of the data submitter. If the data are not supportive, possible alternative action(s) that may be taken by the registrant, such as label modification, are suggested. If deficiencies/omissions exist in the submitted data, the reviewer may have to defer judgment until such time as appropriate corrective action has been rendered by the registrant.

APPENDIX 1

INFORMATION REQUESTED OF THE REGISTRANT

The registrant's report on terrestrial field testing studies should include all information necessary to provide: 1) a complete and accurate description of the field treatments and procedures, 2) sampling data and phytotoxicity rating, 3) data on storage of the plant material, if so performed, 4) any chemical analysis of the plant material as to chemical content, if so performed, 5) reporting of the data, rating system and statistical analysis, and 6) quality control measures/precautions taken to ensure the fidelity of the operations.

Specifically, each laboratory/greenhouse/small field plot terrestrial field testing report should include the following information:

I. General

° Cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study;

° Name (and signature), title, organization, address, and telephone number of the person(s) responsible for planning/supervising/monitoring and, for field plot studies, applying the pesticide;

° Trial identification number;

° Quality assurance indicating: control measures/precautions followed to ensure the fidelity of the phytotoxicity determinations; record-keeping procedures and availability of logbooks; skill of the laboratory personnel; status of the field and supporting laboratory equipment; degree of adherence to good laboratory practices; and degree of adherence to good agricultural practices in maintaining healthly plants; and

° Other information the registrant considers appropriate and relevant to provide a complete and thorough description of the test procedures and results.

II. Test Substance (Pesticide)

° Identification of the test pesticide active ingredient (ai) including chemical name, common name (ANSI, BSI, ISO, WSSA), and Company developmental/experimental name;

° Active ingredient percentage in the end-use product or representative end-use product from the same major formulation category for that general use pattern;

° Dose rate(s) in terms of active ingredient per area of land or of leaf (if leaf-area-index is provided);

° Dose rate(s) in terms of less than the maximum label rate with dosages in a geometrical progression of no more than two-fold and with subtoxic (< EC_{50} level) and non-toxic (no-observable-effect-level) concentrations;

° Method of application including equipment type (nozzles, orifices, pressures); and

° Number and timing of applications.

III. Plant Species

° Identification of the plant species used. They shall be representatives of the following plant groups:

Dicotyledonae (dicots)	3 Families
Monocotyledonae (monocots)	3 Families
Vascular Cryptogamae (ferns and allies)	2 Families
Bryophyta (mosses) or Hepatophyta (liverworts) (Wetland use patterns only)	1 Family
Gymnospermae (conifers)	1 Representative

° Identification of the cultivar(s) of the plant species used, where possible;

° Identification of the number of replicates and the number of plants per replicate per dose; and

° Identification of the date of planting, date of pesticide application, and date of phytotoxicity rating or harvest.

IV. Site of the Test

° Site description of the terrestrial field testing study such as a grassland, forested area, fallow field, tilled field, etc.;

° Location of the test site(s) that represent the general regional areas of potential usage as noted below:

Northeastern temperate deciduous
Southeastern temperate deciduous
Northern grassland (cool prairie)
Southern grassland (warm prairie)
Northwestern (and Alaskan) conifer forest and high desert
Southwestern chaparral Mediterranean and low desert
Hawaiian and Caribbean semi-tropical and tropical regions

° Climatological data during the test (records of applicable conditions for the type of site, i.e., temperature, thermoperiod, rainfall or watering regime, light regime - intensity and quality, relative humidity, wind speed);

° Field lay-out (for field plots), e.g., size and number of control and experimental plots; number of plants per plot/unit area;

° Population density of seeds or plants;

° Cultural practices such as cultivation and irrigation; and

° Substrate characteristics of the site(s) (name/designation of soil type and its physical and chemical properties, including pH and percent organic matter, presence and depth of fragipan or shallow bedrock, etc.).

V. Results

° Phytotoxicity rating (including a description of the rating system) for each plant or group of plants (population) in the test;

° Weight, height or other growth parameters that may have been measured to ascertain toxic effects of the pesticide upon the plants; and

° Statistical analysis of the results including environmental or effective concentration (EC) values.

VI. Evaluation

° Determination as to whether additional phytotoxicity testing will be necessary to characterize the phytotoxic nature of the chemical.

APPENDIX 2

SPECIFIC QUESTIONS FOR THE REVIEWER

The following questions are provided to aid the reviewer in performing the standard evaluation procedure in a scientific manner and in acquiring the necessary information to complete a standard format for preparation of scientific reviews.

I. General

° Were the name of the cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study provided?

° Were the name (and signature), title, organization, address, and telephone number of the person(s) responsible for planning/supervising/monitoring and, for field plot studies, applying the pesticide provided?

° Was the trial identification number provided?

° Were quality assurance control measures/precautions indicated?

II. Test Chemical

° Was the test chemical used the end-use product or a representative end-use product from the same major formulation category for that general use pattern?

° Was the active ingredient percentage of the chemical given?

° Were the doses given in quantity per unit area (of plant or land surface) or tank concentrations?

° Was the maximum dose less than the maximum label rate?

° Were the additional dosages of a geometric progression of no more than two-fold, e.g., 0.1, 0.2, 0.4, 0.8, 1.6 kg/ha?

° Were a subtoxic ($< EC_{50}$) and a non-toxic concentration evaluated?

III. Test Species

° Were representatives from the following groups included in the studies?

Dicotyledonae (dicots)	3 Families
Monocotyledonae (monocots)	3 Families
Vascular Cryptogamae (ferns and allies)	2 Families
Bryophyta (mosses) or Hepatophyta (liverworts) (Wetland use patterns only)	1 Family
Gymnospermae (conifers)	1 Representative

Where seed germination/seedling emergence studies have been performed, seeds of plants with low or variable germination potential should have been avoided. Some seeds of questionable species and varieties should have been pretested for viability.

° If any plant group is not likely to be exposed to the pesticide under normal conditions of use, testing of such groups is not required. Was justification for elimination of a test species or group included in the test report?

° Where various cultivars could be used, such as in the case of most agronomic and horticultural plants, were cultivar or varietal names provided? Were the plant and seed sources identified?

° Were there at least three replicates with five plants per replicate for each dose?

° Were the plants healthy and not in a state of stress?

° Were the plants in a stage of development under which the pesticide would be normally applied?

° If surrogate plant species were used to represent those of the natural habitat, were such relationships identified?

° Were endangered or threatened plant species not used?

IV. Test Procedures

° Were the locations of the test site(s) within the following general geographical regions in which the pesticide is to be used provided?

Northeastern temperate deciduous
Southeastern temperate deciduous
Northern grassland (cool prairie)
Southern grassland (warm prairie)
Northwestern (and Alaskan) conifer forest and high desert
Southwestern chaparral Mediterranean and low desert
Hawaiian and Caribbean semi-tropical and tropical regions

° Was the test site specified, i.e., small field plot or large field plot?

° Were the environmental conditions that prevailed during the test (temperature, thermoperiod, light regime - intensity and quality, rainfall or watering regime, relative humidity, wind) provided as appropriate for the site?

° Were the environmental conditions that prevailed during the test those most favorable and most typical to the growth of the plants used? Were the conditions referenced?

° Was the test duration two weeks to four weeks in length?

° If multiple applications are directed on the label, were they made and did the observations extend at least two weeks past the last application?

° Was the test substance applied over a period of time or season according to the proposed label instructions?

° Was the method of pesticide application including the type of application equipment given?

V. Reporting

° Were the detrimental effects reported as severity of phytotoxicity (rating or percentage)?

° If a rating system was used, was an explanation provided?

° Were observations to note plant growth and response to the pesticide taken at least twice weekly?

° Were abnormal changes in growth, development, and/or morphology reported as compared to the controls?

° Though not required, were direct measurements of height, weight, or other growth parameters provided?

VI. Evaluation

° Were the results tabulated to indicate a percentage effect level for each species as compared to the untreated control plants?

° Were 25 and 50 percent detrimental effect levels determined for those plant species of Tier 2 that showed a phytotoxic effect to the chemical?

° Was a determination made as to whether additional terrestrial field phytotoxicity tests were necessary to evaluate the effects of the pesticide on non-target plants?

APPENDIX 3

SAMPLE STANDARD FORMAT FOR PREPARATION OF SCIENTIFIC REVIEWS

The following format shall be used in documenting the review of the Subdivision J - Hazard Evaluation: Non-Target Plants - Tier 3 - Terrestrial Field Testing Study.

Chemical: (Common Name)

Formulation: (Percent Active Ingredient)

Study/Action: (Purpose of the Submission)

Study Identification:

(Subdivision J Test Title)
(Reference or Registrant Data Information with Study Number)
(EPA Accession Number)

Reviewer: (Name and Address of Reviewer; Date of Review)

Approval: (Quality Control Reviewer)

Conclusions: (Summary and Conclusion of Tests)

Acceptability and Recommendations:

(Decide as to (1) the scientific validity of the study and (2) compliance to the Subdivision J - Terrestial Field Testing guidelines)

Background: (Introductory Information and Directions for Use)

Discussion:
1. Study Identification
2. Materials and Methods
3. Reported Results
4. Reported Conclusions
5. Reviewer's Interpretation of Results and Conclusion

REFERENCES

Little, T. M., and F. J. Hills. 1978. Agricultural Experimentation - Design and Analysis. New York: John Wiley and Sons.

Truelove, B., ed. 1977. Research Methods in Weed Science. Southern Weed Science Society. Auburn, AL: Auburn Printing Inc.

Other scientific articles of seed germination may be found in the following journals:

Agronomy Journal
Environmental Science and Technology
Journal of Environmental Quality
Soil Science and Plant Nutrition
Weed Science